This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K050148

Contact Person: Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Telephone: 805-879-6304
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Date Prepared: January 21, 2005

Device Name and Classification

Proprietary Name:	Mentor Aris Trans-obturator Tape and Surgical Kit
Common Name:	Pubourethral Support Tape
Classification Name:	Surgical Mesh, polymeric
Class:	Class II
Product Code:	FTL
CFR #:	§878.3300

Device Description

The Mentor Aris Trans-obturator Kit consists of two components: the Mentor Aris Trans-obturator Tape and a set of introducer needles.

The Mentor Aris Trans-obturator Tape is an implantable, suburethral, support tape made from knitted monofilament polypropylene fibers. This structure gives the Aris Tape resistance to traction, allows tissue colonization and facilitates positioning during surgery.

A set of sterile, disposable Introducer Needles (one flat curved introducer and a pair of helical introducers) necessary for implantation of the tape are also included in the Surgical Kit.

Substantial Equivalence Claim

The Mentor Aris Trans-obturator Tape and the Kit are substantially equivalent in material, function, performance and design to the Mentor ObTape Trans-Obturator Tape

and Surgical Kit cleared under 510(k)s K031767 and K042851, respectively. It is also substantially equivalent to other urethral support tape products currently on the market..

Indications for Use

Mentor Aris Trans-obturator Surgical Kit consists of the Mentor Aris Trans-obturator Tape, an implantable, suburethral, support tape, plus introducers. The Tape and the Surgical Kit are indicated for the surgical treatment of all types of stress urinary incontinence (SUI), and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Summary of Testing

All mechanical, biological, and chemical testing specifications comply with established ISO, USP, EN and/or NF standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 - 2005

Ms. Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, California 93111

Re: K050148
Trade/Device Name: Mentor Aris Trans-obturator Tape and Surgical Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Polymeric surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: January 21, 2005
Received: January 24, 2005

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K050148

Device Name: Mentor Aris Trans-obturator Tape and Surgical Kit

Indications for Use:

The Mentor Aris Trans-obturator Surgical Kit consists of the Mentor Aris Trans-obturator Tape, an implantable, suburethral, support tape, plus introducers. The Tape and the Surgical Kit are indicated for the surgical treatment of all types of stress urinary incontinence (SUI), and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over the Counter Use _____
(Per CFR 801.109)

(Optimal Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050148